UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In Re Novartis and Par Antitrust Litigation	**ORDER GRANTING MOTION TO COMPEL DISCOVERY** 18 Civ. 4361 (AKH)

ALVIN K. HELLERSTEIN, U.S.D.J.:

Plaintiffs move pursuant to Federal Rule of Civil Procedure 45 for an order compelling nonparties Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") to produce various materials responsive to a subpoena. *See* Motion to Compel, ECF No. 244. For the reasons set forth below, Plaintiffs' motion to compel is granted, with the caveat that Plaintiffs must cover the cost of Lupin's compliance with the subpoena going forward. Familiarity with the basic facts of this dispute, which I have described in a prior order, *see* Order (Aug. 15, 2019), ECF No. 193, is assumed.

Background[1]

A. Underlying Litigation

In this civil antitrust action, Plaintiffs allege that the Defendants——Novartis Pharmaceuticals Corporation and Novartis AG (together, "Novartis") and Par Pharmaceutical, Inc. ("Par")——entered into an unlawful agreement to delay the entry of generic competition to brand-name drug "Exforge," a prescription drug used to treat hypertension. In that agreement, Par agreed not to launch a generic version of Exforge until September 30, 2014 and Novartis in

[1] The following facts are drawn from the operative complaint and from the memorandums of law submitted in connection with this motion (along with exhibits attached thereto).

turn agreed not to compete with Par by launching its own generic version of Exforge for the 180-day regulatory exclusivity period following Par's entry to the market. Plaintiffs contend that, but for the agreement, Par would have come to market with its generic Exforge before September 30, 2014, triggering an earlier start of the 180-day exclusivity window, which would have resulted in other generic competitors, such as Lupin, entering the generic Exforge market prior to March 30, 2015 (when the 180-day exclusivity period in fact ran out), and lowering Exforge's market price. *See* Amended Complaint, ECF No. 139, at ¶¶ 1-11.

Embedded in the Plaintiffs' complaint is a key assumption: that Lupin or some other "generic competitor … had the capacity, capability[,] and economic incentive to enter the market earlier absent the Novartis/Par reverse payment agreement." Pl. Mem. in Support of Mtn. to Compel, ECF No. 245, at 1. In other words, if generic competitors were, for whatever reason, incapable of entering the market prior to March 30, 2015 even if they had wanted to do so, then it cannot be said that the alleged Novartis/Par agreement "delayed competition from lower-priced generic versions of Exforge." Amended Compl. at ¶ 10.

B. The Subpoena

Plaintiffs served Lupin with the subpoena at issue in this motion on February 11, 2019.[2] Notice of Service of Subpoena *Duces Tecum* (the "Subpoena"), ECF No. 246-1.

[2] The record reflects that, prior to serving the February 11, 2019 subpoena, Plaintiffs served an earlier version for the same request in December, upon which the parties met and conferred, and which Plaintiffs later withdrew in favor of serving the February 11, 2019 iteration of the subpoena. The record also reflects that in January 2019, Plaintiffs also served a subpoena on Novel Laboratories, Inc., a subsidiary of Lupin, seeking similar information. *See* Declaration of Zarema Jaramillo, ECF No. 250, at ¶¶ 1-6 and 2 n.1. Because Plaintiffs have only moved to compel production in relation to the February 11, 2019 subpoena, I do not address the withdrawn December 2018 subpoena or the request for production made on Novel Laboratories.

Therein, Plaintiffs made, *inter alia*, two requests targeted to documents probative of Lupin's ability, plan, incentives, and so on, to enter the generic Exforge market:

> Documents Concerning Market Entry of Generic Exforge …
>
> 4. All documents concerning Your, Par's, Novartis's or any other company's actual, proposed, or contemplated plans for launching Generic Exforge or Generic Exforge HCT, including the following: (i) launch timelines, new product launch meeting minutes, projections, and forecasts, including any assumptions used; (ii) schedules; (iii) launch updates, action items from new product launch meetings, and launch team meeting minutes; (iv) "at-risk" launch analyses and discussions; (v) manufacturing forecasts; (vi) sourcing of active and inactive ingredients (including communications with any suppliers); (vii) exhibit batches, scale up, validation, building and maintenance of commercial quantities, and/or manufacture, sale, transfer, or destruction of same; and (viii) public statements (including statements to investors or courts) and competitive intelligence.
>
> 5. All documents concerning any regulatory, legal, technical, manufacturing, or other issues or reasons why You or any other Generic Exforge ANDA filer could or could not or would or would not commercially launch a Generic version of Exforge prior to September 30, 2014, including but not limited to:
>
> > a. All documents concerning the manufacturing sites, facilities, equipment, and other resources proposed, contemplated, or actually used in the development, regulatory approval, scale-up, validation, commercial manufacturing, and launch of Generic Exforge;
> >
> > b. All documents concerning CGMP, inspections, manufacturing, quality control, or quality assurance regarding any manufacturing sites, facilities, or equipment proposed, contemplated, or actually used in the development, regulatory approval, scale-up, validation, commercial manufacturing, and launch of Generic Exforge;
> >
> > c. All documents relating to potential or actual suppliers of active and inactive ingredients, container/closure systems, labeling, tooling, or other vendors of products or services for Generic Exforge, including, but not limited to, communications with any such company(ies); orders and cancellation of orders; invoices and payments; contracts (including amendments and supplements thereto); drafts of contracts; compliance with contracts; disputes; settlements of disputes; forecasts; projections; manufacturing ability; supply requirements; production schedules; supply schedules; product marketing; product launch dates internal memorandum; emails; meeting agendas and minutes; transcripts of conversations; and drug master files;

> d. All documents relating to actual and theoretical manufacturing capacity and the rate limiters on that capacity, including any shortages in raw materials, manufacturing sites and/or equipment, or other rate limiters for Your Generic Exforge product;
>
> e. Documents sufficient to show the amount of inventory expressed in terms of weeks or months on hand of inventory that You had of Generic Exforge at the time of anticipated launch and/or at the time You actually launched Your Generic Exforge product;
>
> f. Documents sufficient to show batch sizes, manufacturing process, throughput times per batch, and manufacturing rates for Your Generic Exforge product.

Subpoena at 8-10. Thereafter, the parties extensively negotiated the scope of the subpoena, in so doing reaching agreements on a number of Plaintiffs' request, but failing to resolve disagreement as to Requests 4 and 5 quoted above. *See, e.g.* Pl. Mem. at 6 n.15 (listing at least 25 occasions in which the parties have exchanged letters or met via phone or in-person). Over the course of the negotiations, Lupin made, by my count, somewhere in the range of six document productions to Plaintiffs, totaling over 1,100 documents and 20,000 pages. *See* Jaramillo Decl. at ¶¶ 10-35.[3]

In April 2020, Lupin wrote to Plaintiffs and stated that, following a reasonable search, Lupin was unable to find any additional responsive documents and Lupin was of the view that it had fully complied with the subpoena:

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[3] Plaintiffs represent in their briefing that "[d]uring negotiations, Lupin confirmed its express understanding of the nature of the documents sought … and never claimed the documents were not available to too burdensome to produce." Pl. Mem. at 6; *see also id.* at 17-18 ("This Court … should order Lupin to comply with its discovery obligations and promptly produce the documents it agreed to produce almost a year ago." Plaintiffs also refer to these as the "Agreed-Upon Documents" throughout their papers. *See id*. at 10, 12. But a close reading of the correspondence cited by Plaintiffs does *not* show that Defendants "agreed" to any such production. Instead, in the letter principally referenced, Lupin describes Plaintiffs' document requests and then goes on to suggest that Plaintiff cover the costs of the production. *See* Letter from Lupin to Plaintiffs (Apr. 19, 2019), ECF No. 246-2 ("Please confirm that, should Lupin agree to produce … documents responsive to Requests No. 4 and 5 that are in its possession, custody, or control, Plaintiffs will reimburse Lupin for the reasonable costs of complying with the Subpoena.") Plaintiffs selectively quote from the letter but omit this critical sentence——this comes uncomfortably close to the line that separates framing the facts from misrepresentation.

> Lupin … ha[s] fully complied with Plaintiffs' Subpoenas, through a series of rolling productions made to Plaintiffs….
>
> Plaintiffs nonetheless demand that Lupin produce additional "launch preparation documents. In addition to producing its entire ANDA file for generic Exforge and generic Exforge HCT, which shows that Lupin did not have FDA approval to launch generic Exforge until March 2015, Lupin also produced to Plaintiffs its New Product Launch meeting minutes describing Lupin's launch plans for generic Exforge and generic Exforge HCT, as well as other documents reflecting Lupin's ability to scale-up and launch Generic Exforge and Generic Exforge HCT. For the avoidance of doubt, following a reasonable search, Lupin has located no other non-privileged documents responsive to Requests 4 and 5 of Plaintiffs' Subpoena of Lupin.

Letter from Lupin to Plaintiffs (Apr. 17, 2020), ECF No. 246-3. Plaintiffs do not share Lupin's view that the production is sufficient, and identify nine categories in which Lupin's production is purportedly deficient:

> 1. Process validation reports for all four strengths of Lupin's Generic Exforge.
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> 2. Process validation batch manufacturing records for all four strengths of Lupin's Generic Exforge.
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> 3. New Product Launch Meeting minutes for Lupin's Generic Exforge from the date launch planning began until April 1, 2015.
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> 4. Documents sufficient to show the amount of generic Exforge finished product inventory that Lupin had on hand at the time of launch on March 30, 2015 and the date Lupin began to manufacture that inventory.
>
> 5. Lupin's generic Exforge launch timeline(s) showing planned and completed tasks in preparation for launch starting on January 1, 2011 and ending on April 1, 2015.
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> 6. Documents sufficient to show when Lupin ordered the required active pharmaceutical ingredients ("API"), other excipients, and packaging intended for use in its first commercial batches of generic Exforge manufactured for its March 30, 2015 launch, and in what quantities.
>
> 7. Documents between January 1, 2011 and March 30, 2015 sufficient to show the extent to which, if at all, Lupin considered and took steps towards launching generic Exforge earlier than March 30, 2015. This may include launch timelines,

> purchases of API or other excipients, manufacturing of process validation batches, or internal correspondence indicating a proposed launch date.
>
> 8. Documents sufficient to show whether Lupin encountered any difficulties in manufacturing its commercial batches of generic Exforge in preparation for its March 30, 2015 launch.
>
> 9. Documents sufficient to show when Lupin purchased or made available the equipment used in the manufacturing of generic Exforge commercial batches in advance of its March 30, 2015 launch.

Pl. Mem. at 2-3.

C. Procedural History

On May 29, 2020, Plaintiffs filed this motion to compel Lupin to produce additional documents in response to Plaintiffs' subpoena——specifically, to produce documents in the nine categories quoted above——and a supporting brief with accompanying exhibits. *See* ECF Nos. 244, 245, 246. Lupin has filed its opposition, also with accompanying exhibits. *See* ECF Nos. 249, 250. The motion became fully briefed on June 17, 2020. *See* ECF No. 251.

Discussion

A. Legal Principles

1. Subpoenas of Non-Parties under Rule 45

Federal Rule of Civil Procedure 45 "allows a party to serve a subpoena on a non-party for the production of documents." *Mackey v. IDT Energy, Inc.*, No. 19 Misc. 29, 2019 WL 2004280, at *3 (S.D.N.Y. May 7, 2019); *see* Fed. R. Civ. P. 45(a). Motions to compel discovery are subject to a "two-step analytical framework": First, the moving party must demonstrate that the information sought is "discoverable"; second, once discoverability has been shown, "it is up to the responding party to justify curtailing discovery." *In re Namenda Dir. Purchaser Antitrust*

Litig., No. 15 Civ. 7488, 2017 WL 3822883, at *4 (S.D.N.Y. Aug. 30, 2017) (quotation marks and alterations omitted) ("*In re Namenda*").

The scope of what is properly discoverable is affixed by Federal Rule of Civil Procedure 26, which provides in pertinent part that parties may obtain discovery

> regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.
>
> ….
>
> On motion or on its own, the court must limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that … [among other things,] the discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive.

Fed. R. Civ. P. 26(b). As such, Rule 26 limits discovery to matters that are, *inter alia*, "relevant" and "proportional" to the case's needs. *Id.* If the party issuing the subpoena establishes that the materials sought are relevant, "the burden then shifts to the [third party] to demonstrate an undue burden." *Mackey*, 2019 WL 2004280, at *3.

Whether a "subpoena imposes an undue burden depends on such factors as relevance, the need of the party for the documents, the breadth of the document, the time period covered by it, the particularity with which the documents are described and the burden imposed." *Id.* (quotation marks omitted). And if, as here, the "subpoena seeks discovery from a non-party," the court may consider "the expense or inconvenience that compliance would cause." *Id.* Trial courts have "broad discretion to determine whether a subpoena imposes an undue burden," *id.*, but in the case of subpoenas targeted at nonparties, should be "particularly sensitive to weighing

the probative value of the information sought against the burden of production to the nonparty," *UMB Bank, NA v. Sanofi*, No. 15 Civ. 8725, 2017 WL 6398628, at *1 (S.D.N.Y. Nov. 22, 2017); *see also, e.g., In re Namenda*, 2017 WL 3822883, at *4 ("Litigants and courts are instructed to be especially solicitous of non-party targets of subpoenas."); *MacNamara v. City of New York*, No. 04 Civ. 9612, 2006 WL 3298911, at *15 (S.D.N.Y. Nov. 13, 2006) (courts "give special weight to the burden on non-parties of producing documents to parties involved in litigation"); *but see In re Namenda*, 2017 WL 3822883, at *4 ("Inconvenience alone" to a non-party is not enough to justify noncompliance with a subpoena).

Claims of undue burden must "explain the manner and extent of the burden, as well as the consequences of compliance." *Id*. at *9. Due to the importance of context in gauging the propriety of a Rule 45 subpoena, assessing undue burden is "a highly case specific inquiry." Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2463.1 (3d ed. 2008).

2. Cost-Shifting

Courts in this district have found "[c]ost-shifting … particular appropriate in the context of subpoenas, since Rule 45 directs courts to minimize the burden on non-parties." *Id.* at *10 (quotation marks omitted). In determining whether cost-shifting is warranted, the following factors are often considered: "(1) whether the party has an interest in the outcome of the case; (2) whether the nonparty can more readily bear the costs; and (3) whether the litigation if of public importance." *In re World Trade Center Disaster Site Litig.*, No. 21 Mc. 100, 2010 WL 3582921, at *1 (S.D.N.Y. Sept. 14, 2010); *see also In re Namenda*, 2017 WL 38228823, at *10 (shifting costs where the object of the subpoena was a non-party and there was "no indication" that the non-party was better situated to "pay the costs of document production" than plaintiffs); *Kenyon v. Simon & Schuster, Inc.*, No. 16 Misc. 327, 2016 WL 5930265, at *7 (S.D.N.Y. Oct. 11, 2016)

(inviting the non-party to "apply … for cost-shifting if the costs of responding to the subpoena become too onerous"); Fed. R. Civ. P. 45 Application Note ("A non-party required to produce documents or materials is protected against significant expense resulting from involuntary assistance to the court.").

B. Application

Lupin first argues that it has "produced to Plaintiffs more than 20,000 pages of responsive material," and that the production already accomplished "appropriately balances the parties' need for this discovery against Lupin's rights to avoid undue burden and expense as a non-party." Def. Opp. Mem., ECF No. 249, at 7. Lupin contends that its "production—— including [Lupin's] forecasts, ANDA file, New Product Launch meeting minutes, transactional data, and launch preparation documents——is sufficient" for purposes of fleshing out Plaintiffs' theory that Lupin could have entered Exforge generics market earlier than it ultimately did. *See id*. at 8. Next, Lupin argues that Plaintiffs' subpoena is unduly burdensome, contending that the "nine categorical requests are sweepingly broad" and further that "Lupin has been unable to locate and produce responsive documents despite more than 18 months of" reasonable, good-faith searches. *Id.* at 9.

Plaintiffs' production request is broad, and complying with Plaintiffs' subpoena would impose a burden on Lupin. *See generally* Jaramillo Decl. (describing eighteen months of document searches and also noting that at least at least certain "manufacturing documents" requested by Plaintiffs are housed in a facility based in India, which is "inaccessible" as it is under "complete lockdown" due to the COVID-19 pandemic).

However, the materials requested by the subpoena are relevant to this complex dispute. For instance, if "generic Exforge launch timeline(s)" were to show that Lupin was

willing and able to enter the generic Exforge market prior to the expiration of Par's exclusivity period, this would clearly be probative of Plaintiffs' claim that the Novartis/Par agreement delayed would-be entrants to the market. Lupin hardly contests relevance, mustering as a response only that (1) Lupin is mentioned by name only four times in Plaintiffs' complaint, *see* Def. Opp. Mem. at 2, and (2) unlike in other cases involving Lupin, *see, e.g.*, *In re Namenda*, 2017 WL 3822883, here Lupin was not a party to the settlement with Novartis that is challenged in the underlying litigation, *see* Def. Opp. Mem. at 10. Neither claim changes the fact that the ability of third-parties to enter the Exforge generics market lies at the core of Plaintiffs' case for damages .

These competing conclusions can easily be managed by shifting costs such that Plaintiffs will pay Lupin for reasonable expenses and attorneys' fees incurred in complying with Plaintiffs' production request going forward. Indeed, *In re Namenda*, upon which Plaintiffs rely throughout their briefing, reached precisely this same result. *See* 2017 WL 3822883, at *10. As Lupin is neither a party to this litigation nor accused by Plaintiffs' of wrongdoing, at some point the breadth of Plaintiffs' production demands border on punitive. *Cf. Wells Fargo Bank, N.A. v. Konover*, 259 F.R.D. 206, 207 (D. Conn. 2009) ("In determining whether the requesting party should be required to bear the costs of production, a number of courts have looked to whether the non-party was substantially involved in the underlying transaction and could have anticipated that such transaction could potentially spawn litigation or discovery."). And nothing in the record indicates that Plaintiffs are unable to cover these costs as compared to Lupin. *See id.* In sum, Lupin shall comply with the "narrowed Request Nos. 4-5" by producing documents that fit the nine categories outlined by Plaintiffs, *see* Pl. Mem. at 2-3, 18, but the burden triggered by this compliance will be addressed by Plaintiffs covering Lupin's reasonable fees and expenses.

Conclusion

For the foregoing reasons, the motion to compel discovery is granted. Plaintiffs shall pay to Lupin the reasonable expenses and attorneys' fees incurred in complying with this motion going forward. Lupin shall produce the requested documents within 45 days from the issuance of this order. The Clerk is instructed to close the open motion (ECF No. 244).

SO ORDERED.

Dated: June 18, 2020
New York, New York

_____/s/_____
ALVIN K. HELLERSTEIN
United States District Judge